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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,322	02/25/2004	Daniel M. Lafontaine	10527-437002	2641
26191	7590	02/13/2009		
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER GIBSON, ROY DEAN	
			ART UNIT 3739	PAPER NUMBER
			NOTIFICATION DATE 02/13/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/786,322	Applicant(s) LAFONTAINE, DANIEL M.	
	Examiner Roy D. Gibson	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,44,46,49 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,44,46,49 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Entry of Amendment

Applicant's amendment filed on October 30, 2008 is acknowledged. Claims 43, 44, 46, 49 and 52 are currently pending.

Prior Rejections or Objections

The following comments pertain to the rejections or objections in the most recent Office action mailed on April 18, 2007. Rejections under 35 U.S.C. 102 are withdrawn, however, new grounds of rejection are presented below. The allowability of claims 50 and 52 are withdrawn, therefore, this Office action is non-final.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 52 is rejected under 35 U.S.C. 102(e) as being anticipated by LePivert (6,551,309). LePivert discloses a device comprising:

a tubular member (13) having a proximal end and a distal end;

a cryo-therapy apparatus comprising an inner chamber and an outer chamber (Figure 9 and inner chamber 29 and outer chamber 30) and connected to the distal end of the tubular member, the outer chamber arranged and configured to prevent loss of coolant if the inner chamber fails;

Art Unit: 3739

and an optical imaging apparatus (CIS device # 17) near the distal end of the tubular member to monitor temperatures resulting from use of the cryo-therapy apparatus,

wherein the cryo-therapy apparatus is sized and arranged for vascular introduction (col. 6, line 59-col. 7, line 23, col. 8, lines 60-66 and col. 11, lines 27-42).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43, 44, 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over LePivert in view of Hammack et al. (6,679,906). LePivert discloses a device comprising:

a tubular member (13) having a proximal end and a distal end;

a cryo-therapy apparatus connected to the distal end of the tubular member, wherein the cryo-therapy apparatus comprises an inner chamber and an outer chamber; and wherein the cryo-therapy apparatus is sized and arranged for vascular introduction (outside shaft diameter between 1.8 and 3.3 mm and col. 8, lines 60-66).

But LePivert fails to specifically disclose an optical sensor to monitor temperatures created by use of the cryo-therapy apparatus, the optical sensor coupled

Art Unit: 3739

to a retractable member capable of moving independently of the cryo-therapy apparatus;

further comprising a temperature quantification device in communication with the optical sensor;

wherein the optical sensor is positioned to observe ice or ice ball formation created by the cryo-therapy apparatus; and

wherein the optical sensor is disposed at least partially within a lumen defined in the tubular member. However, Hammack et al. discloses a catheter with on on-board optical temperature sensor which meets all of the above limitations not disclosed by LePivert (Figures 1-5 and col. 10, lines 36-51). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of LePivert, as taught by Hammack et al., to provide the optical sensor, quantification device and separate lumen as required for monitoring the ice ball formation and temperature.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/
Primary Examiner
Art Unit 3739

February 10, 2009